

**Remarks**

This Amendment is in response to the Office Action dated **December 12, 2007**.

Claims 1-27, 36 and 37 are pending in this application. The Office Action rejected claims 1-12, 14-27, 36 and 37 under 35 USC § 103 over Lee (US 5203777) in view of Kittrell (US 4718417); and rejected claim 13 under 35 USC § 103 over Lee in view of Kittrell and further in view of Pacetti (US 6574497).

By this Amendment, dependent claims 9, 11, 14, 19 and 22 are amended. Support for the amendments can be found at least in Figures 2, 9 and 10, and in the specification at page 8, lines 27-30 and page 9, lines 3-13. Applicants reserve the right to prosecute any cancelled subject matter in a subsequent patent application claiming priority to the immediate application.

Reconsideration in view of the above amendments and the following remarks is respectfully requested.

**Claim Rejections**

The Office Action rejected, under 35 USC § 103, claims 1-12, 14-27, 36 and 37 under 35 USC § 103 over Lee in view of Kittrell; and claim 13 over Lee in view of Kittrell and further in view of Pacetti.

The rejections under 35 USC § 103 are traversed because the applied references do not disclose or suggest the device defined by the rejected claims. The rejection proposes a modification to Lee, however, the modification goes beyond the teachings of the applied references. The actual motivation for the modification appears to stem from an impermissible use of hindsight in an attempt to reach the pending claims. A person having ordinary skill in the art and using common sense would not have been led to a device described by the pending claims.

Lee teaches a marking system having a first marker 60 and a second marker 62, wherein the markers 60, 62 are preferably rectangular in shape and made of metal foil. See Figure 2, provided below and column 5, lines 5-14.

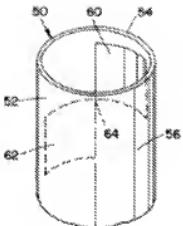


FIG. 2

The rejection states:

Although Lee does not explicitly disclose that this metal is shaped into a wire, it is obvious to one skilled in the art to use wires as the marker on a medical device as can be seen in Kittrell. Kittrell teaches using radiopaque markers in the shape of a metal band or wire.

See Office Action at page 3.

Kittrill teaches a visible fluorescence spectral diagnostic device for laser angiosurgery. See Abstract and Figure 1, provided below.

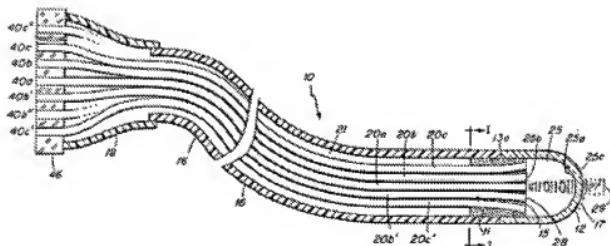


FIG. 1

An optical shield 12 is provided at the end of the device and secured to the catheter 16 by a joint 13a. See column 7, line 65-column 8, line 5 and Figure 1, above. Laser radiation is delivered through the optical shield 12 to a treatment location, and reflected laser light passes back through the optical shield 12, through optical fibers 20a-c and out of the device where it can be analyzed. See column 9, lines 15-28.

Kittrell further teaches that radiopaque material can be incorporated into the device. For example, Kittrell states, "A metal band or wire 13f,g,h, shown in FIGS. 7A-D, may

be placed around the laser catheter 10 near the distal end, which can serve both as a radio-opaque marker and provide mechanical support to the optical shield 12.” See column 9, lines 35-39. See also Figures 7C and 7D, provided below.

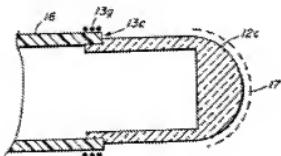


FIG. 7C

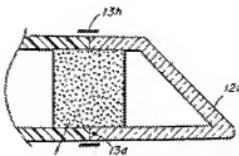


FIG. 7D

Thus, Kittrell's teaching of a “wire marker” is limited to a teaching of multiple windings of wire that collectively form a band of material, similar to the band 13h illustrated in Figure 7D. The wire band serves multiple purposes in providing radiopacidity and also reinforcing the joint 13 between the optical shield 12 and the catheter 16.

The Office Action asserts that in light of Kittrell, it would have been obvious to replace the Lee markers 60, 62 with wire loops shaped according to the boundary of the Lee foil markers 60, 62. See Office Action at page 3.

Applicant asserts that Kittrell's mere disclosure of a wound-wire marker band at the end of a catheter provides absolutely no motivation to redesign the Lee foil markers as proposed in the rejection. A person of ordinary skill in the art would recognize that the foil markers occupy a relatively large area of space, and that the area of material provides visibility under fluoroscopy. There is no teaching in Lee or Kittrell that would provide a common sense rational to a person of skill in the art to replace Lee's foil areas with a wire shaped according to the boundary of the foil areas – as such, the proposed modification appears to stem from impermissible hindsight.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. See *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Prior art references must be considered as a whole and suggest the desirability, and thus the obviousness, of making the combination. See *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 221

USPQ 481 488 (Fed. Cir. 1984).

The applied references do not provide any teaching that wire loops would be suitable for use in the Lee invention. A person of ordinary skill in the art would recognize that an area of metal foil would appear different from a wire loop under fluoroscopy. The rejection has not established that a wire loop would even be desirable when compared to the original Lee foil embodiment. Therefore, the prior art does not suggest the desirability of the proposed modification to Lee, and the basis for the modification appears to be an attempt to produce a device that meets Applicant's claim limitations.

Lee teaches that rectangular markers are preferred, but that squares could also be used if desired. See column 5, lines 5-7. In either case, Lee clearly prefers an area of metal foil. Based upon these considerations, and viewing the references as a whole, a person of ordinary skill in the art would not be motivated to redesign the Lee invention based upon Kittrell's disclosure of "a metal band or wire" that provides radiopacity and reinforces a connection in a catheter.

Further, Lee teaches that an advantage of the Lee invention "is the provision of a marker system which has maximum visibility in a fluoroscopic or X-ray film image." See column 3, lines 27-29. Thus, Lee suggests that the preferred foil embodiment provides maximum visibility. A person of ordinary skill in the art would recognize that modification of the Lee marker in a way that would meet the limitations of the rejected claims could reduce visibility of the device under fluoroscopy, making the modified device less suitable for its intended use than the original Lee device, or even unsuitable for its intended use altogether. Therefore, Applicant asserts that there is no prior art motivation to perform the modification proposed in the rejection.

In light of the foregoing remarks, Applicant asserts that the rejection does not establish a *prima facie* case of unpatentability under 35 USC § 103 against independent claims 1, 15, 36 or 37. Each pending dependent claim is patentable over the applied references for at least the reasons discussed with respect to the independent claim from which it depends.

Pacetti was cited against dependent claim 13 for its teachings relevant to MRI markers. See Office Action at page 4. The addition of Pacetti does not remedy the shortcomings of the rejection discussed above. Pacetti does not provide any motivation to modify Lee or Kittrell in a way that would arrive at a modified device meeting the limitations of the rejected claims.

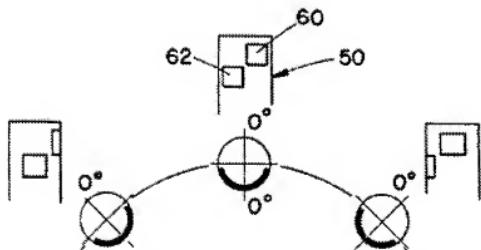
Accordingly, Applicant requests withdrawal of the rejections under 35 USC § 103.

#### Response to Arguments

The rejection asserts that a radiopaque wire and a radiopaque metal foil are “functionally equivalent and will obtain predictable results.” See Office Action at page 3.

The rejection does not provide any prior art teaching that wire and metal foil are “functionally equivalent” to one another within the art of radiopaque markers. A person of ordinary skill in the art would recognize that an area of metal foil would appear different from a wire loop when viewed under fluoroscopy. Therefore, Applicants assert that the rejection has not established a prior art equivalence between wire and metal foil, and a person of ordinary skill in the art would not be motivated to modify Lee to replace foil with wire without an affirmative teaching that the wire would be a desirable alternative to the foil.

The rejection also notes that Figure 4 of Lee illustrates the foil markers as an outline, and asserts that the Figure proves that “the rectangle does not have to be filled to interpret the markers.” See Office Action at page 3 and excerpt from Figure 4, provided below.



Applicant asserts that the rectangles illustrated in Figure 4 likely appear as outlines as an artifact of the black and white patent drawings. A true depiction of a fluoroscopic image would be difficult to create as a black and white line drawing. Thus, the rectangles in Figure 4 likely appear as borders of the foil area for practical reasons, however, the illustration of the border does not translate into a teaching that wire loops would be a suitable replacement for metal foil, or that wire loops would even work in the Lee device.

**Conclusion**

Based on at least the foregoing amendments and remarks, Applicant respectfully submits this application is in condition for allowance. Favorable consideration and prompt allowance of claims 1-37 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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